## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0022]**

### Agency Information Collection Activities Submission for OMB Review; Comment Request

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Submit written comments on the collection of information by October 6, 1997.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Judith V. Bigelow, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1479.

**SUPPLEMENTARY INFORMATION:** In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(a)(2) and (e) (OMB Control No. 0910–0131—Reinstatement)

Under sections 501(c) and 502(a) of the act (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(a)(2) and (e) (21 CFR 801.150(a)(2) and (e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(a)(2) and (e), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices are nonsterile, being shipped for further processing; and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship nonsterile products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices. To discontinue this reporting and recordkeeping procedure would place an economic hardship on the industry and an additional burden on FDA to monitor products in interstate commerce for failure to comply with adulteration and misbranding provisions of the act.

The respondents to this collection of information are device manufacturers and contract sterilizers.

FDA estimates the reporting burden of this collection of information as follows:

TABLE—1. ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 801.150 | 90 | 20 | 1,800 | 4 | 7,200 |

There are no capital costs or operating and maintenance costs associated with this collection of information.

No burden has been estimated for the recordkeeping requirement in § 801.150(a)(2) because these records are maintained as a usual and customary part of normal business activities. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

FDA's estimate of the burden is based on actual data obtained from industry during the past 3 years where there are approximately 90 firms subject to this requirement.

Dated: August 27, 1997.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 97–23507 Filed 9–3–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Memorandum of Understanding Between the Food and Drug Administration and the Department of Agriculture, Food and Forestry of Ireland

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Department of Agriculture, Food and Forestry of Ireland. The purpose of the MOU is to establish certification requirements for caseins, caseinates, and mixtures thereof.

**DATES:** The agreement became effective November 5, 1996.

**FOR FURTHER INFORMATION CONTACT:** Merton Smith, Office of Health Affairs (HFY–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.